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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,980	09/21/2001	Ashley I. Bush	0609.4550001/JAG/FRC	6687
26111	7590	10/26/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/956,980

Applicant(s)

BUSH ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10, 11, 25, 26, 40, 41 and 58-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 25, 26, 40, 41 and 58-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

The allowability of claims 10, 11, 25, 26, 40, 41 and 58-63 is removed so that a new rejection can be made.

Claims 10, 11, 25, 26, 40, 41 and 58-63 are presented for examination.

Applicants' amendment filed June 3, 2004 has been received and entered.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 11, 25, 26 and 58-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 USC 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFA, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

With regard to the *nature of the invention*, a method of treating amyloidosis in a subject, said method comprising administering to said subject an effective amount of a combination of (a) a chelator specific for copper, and (b) clioquinol; wherein said combination reduces, inhibits or otherwise interferes with alpha beta-mediated production of radical oxygen species and prevents formation of alpha beta amyloid, promotes, induces or otherwise facilitates resolubilization of alpha beat deposits, or both.

With regard to the *state of prior art*, the art, applicants' admissions, states clioquinol was withdrawn from use as an oral antibiotic for humans in the early 1970's... was linked to a mysterious condition that resembles subacute combined degeneration of the cord cause by vitamin B12 deficiency... clioquinol may hold promise as an effective agent in the treatment of amyloidosis in humans and Metal chelators offer a powerful tool for investigating the role of metals in the complex environment of the brain, however, the strengths of these compounds may also define their limitation.

With regard to the *level of ordinary skill in the art*, the level of ordinary skill in the art is high.

With regard to the *level of predictability in the art*, the level of the art is not predictable.

With regard to the *amount of direction and guidance provided by the invention*, the specification is rife with hopeful, prophetic language. See, for example, pages 71, 80, 94 and 105. The specification includes such statements as, "Importantly, this results indicates the potential of chelation therapy as a means of reducing amyloidosis".

With regard to the *existence of working examples*, there is no *in vivo* testing present in the examples, there are mainly tests done on cadaver brain tissue.

With regard to the *breadth of the claims*, the claims are drawn to treating amyloidosis.

With regard to the *quantity of experimentation needed to make or use the invention based on the content of the disclosure*, the level of experimentation needed on the unpredictable nature of the invention and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

Claims 10, 11, 25, 26 and 58-61 are not allowed.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40, <sup>41</sup>62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crow et al. (6,022,879) in view of Gerolymatos (5,980,914).

Crow et al. teach the use of bathocuproine, a copper chelator, to treat amyotrophic lateral sclerosis and other neurological diseases, such as Alzheimer's disease. (See the abstract)

The instant invention differs from the cited reference in that the cited reference does not teach the addition of clioquinol with the metal chelator, bathocuproine. However, the secondary reference, Gerolymatos, teach clioquinol as a well-known agent to treat Parkinson's disease, a degenerative neurological disease. Clearly, one skilled in the art would have assumed the combination of two individual agents known for their anti-degenerative effects into a single composition would give an additive effect in the absence of evidence to the contrary.

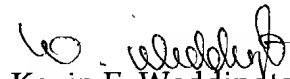
Claims 40, 62 and 63 are not allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7: 30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
October 24, 2004